

(f) *Standards for Part D marketing.* (1) In conducting

marketing activities, a Part D plan may not—

(i) Provide for cash or other remuneration as an inducement for enrollment or otherwise. This does not prohibit explanation of any legitimate benefits the beneficiary might obtain as an enrollee of the Part D plan.

(ii) Engage in any discriminatory activity such as, including targeted marketing to Medicare beneficiaries from higher income areas without making comparable efforts to enroll Medicare beneficiaries from lower income areas.

(iii) Solicit Medicare beneficiaries door-to-door.

(iv) Engage in activities that could mislead or confuse Medicare beneficiaries, or misrepresent the Part D sponsor or its Part D plan. The Part D organization may not claim that it is recommended or endorsed by CMS or Medicare or the Department of Health and Human Services or that CMS or Medicare or the Department of Health and Human Services recommends that the beneficiary enroll in the Part D plan. The Part D organization may explain that the organization is approved for participation in Medicare.

(v) Use providers, provider groups, or pharmacies to distribute printed information comparing the benefits of different Part D plans unless providers, provider groups or pharmacies accept and display materials from all Part D plan sponsors.

(vi) Accept Part D plan enrollment forms in provider offices, pharmacies or other places where health care is delivered.

(vii) Employ Part D plan names that suggest that a plan is not available to all Medicare beneficiaries.

(viii) Engage in any other marketing activity prohibited by CMS in its marketing guidance.

(2) In its marketing, the Part D organization must—

(i) Demonstrate to CMS's satisfaction that marketing resources are allocated to marketing to the disabled Medicare population as well as beneficiaries age 65 and over.

(ii) Establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the

PDP and understand the rules applicable under the plan.

§ 423.56 Procedures to determine and document creditable status of prescription drug coverage.

(a) *Definition.* Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage as demonstrated through the use of generally accepted actuarial principles and in accordance with CMS actuarial guidelines.

(b) *Types of coverage.* The following coverage is considered creditable if it meets the definition provided in paragraph (a) of this section:

(1) Prescription drug coverage under a PDP or MA-PD plan.

(2) Medicaid coverage under title XIX of the Act or under a waiver under section 1115 of the Act.

(3) Coverage under a group health plan, including the Federal employees health benefits program, and qualified retiree prescription drug plans as defined in section 1860D–22(a)(2) of the Act.

(4) Coverage under State Pharmaceutical

Assistance Programs (SPAP) as defined at § 423.454.

(5) Coverage of prescription drugs for veterans, survivors and dependents under chapter 17 of title 38, U.S.C.

(6) Coverage under a Medicare supplemental policy (Medigap policy) as defined at § 423.205.

(7) Military coverage under chapter 55 of title 10,

U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(10) Coverage provided by a PACE organization.

(11) Coverage provided by a cost-based HMO or CMP under part 417 of this chapter.

(12) Coverage provided through a State High-Risk Pool as defined under 42 CFR 146.113(a)(1)(vii).

(13) Other coverage as the Secretary may determine appropriate.

(c) *General disclosure requirements.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, each entity that offers prescription drug coverage under any of the types described in § 423.56(b), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in the coverage whether the coverage is creditable prescription drug coverage.

(d) *Disclosure of non-creditable coverage.* In the case that the coverage of the type described in § 423.56(b) is not creditable prescription drug, the disclosure described in paragraph (c) of this section to Part D eligible individuals must also include:

(1) The fact that the coverage is not creditable prescription drug coverage, as provided by CMS;

(2) That there are limitations on the periods in a year in which the individual may enroll in Part D plans; and

(3) That the individual may be subject to a late enrollment penalty, as described under § 423.46.

(e) *Disclosure to CMS.* With the exception of PDPs and MA-PD plans under § 423.56(b)(1) and PACE or cost-based HMO or CMP that provide qualified prescription drug coverage under this Part, all other entities listed under paragraph (b) of this section must disclose whether the coverage they provide is creditable prescription drug coverage to CMS in a form and manner described by CMS.

(f) *Notification content and timing requirements.* The disclosure notification to Part-D eligible individuals required in § 423.56(c) and (d) must be provided in a form and manner prescribed by CMS. Notices must be provided, at minimum, at the following times:

(1) Prior to an individual's initial enrollment period for Part D, as described under § 423.38(a);

(2) Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;

(3) Prior to the commencement of the Annual Coordinated Election Period that begins on November 15 of each year, as defined in § 423.38(b); and

(4) Upon request by the individual.

(g) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, the individual may apply to CMS to have the coverage treated as creditable prescription drug coverage for purposes of applying the late penalty described in § 423.46.

Subpart C—Benefits and Beneficiary Protections

§ 423.100 Definitions.

As used in this part, unless otherwise specified—

Actual cost means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).

Affected enrollee means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing.

Alternative prescription drug coverage means coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of § 423.104(e). The term alternative prescription drug coverage must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(f)(1)).

Basic prescription drug coverage means coverage of Part D drugs that is either